Attachment 1

DEC 2 2 2010
K101189

5. 510(k) Summary

Trade Name:	ReavillMED Pressure Monitoring System
Common Name:	Blood Pressure Monitoring/Transducer Peripheral Inserted Central Catheter Intravascular Catheter
Classification Name:	Extravascular blood pressure transducer - 21 CFR 870.2850. This device is categorized as DRS and is regulated as Class II. Percutaneous, implanted, long-term intravascular catheter - 21 CFR 880.5970. This device is categorized as LJS and is regulated as Class II. Intravascular catheter - 21 CFR 880.5200. This device is categorized as LJS and is regulated as Class II.
Submitter Information:	ReavillMED LLC 888 E. Belvidere Rd., Suite 212 Grayslake, IL 60030 USA Tel: 847-856-0355 Fax: 847-856-0355
Summary Prepared By:	Michele Vovolka President, Vantage Consulting International, Ltd.
Date Prepared:	December 1, 2010
Predicate Devices:	Utah Pressure Monitoring Device (K842352) Utah Disposable Pressure Transducer (K841788) Bard POLY PER-Q-CATH PICC CATHETERS; POLY RADPICC (K031129) UMBILI-CATH-P (K940871)

Device Description:

The ReavillMED pressure monitoring device is a combination product consisting of the following components within a single device:

- Blood pressure monitoring line and end cap
- Disposable pressure transducer
- Single lumen polyurethane reverse taper catheter
- Catheter hub with suture wing tabs and slip tip cap

The single lumen catheter is packaged within a pressure monitoring line to maintain a sterile environment. A transducer is attached to the distal end of the monitoring line.

The product is sold sterile, single use, and non-pyrogenic.

Indications for Use:

The ReavillMED product is combination product containing a pressure monitoring system and a peripherally inserted central catheter. The pressure monitoring system is intended for continuous measurement of blood pressures or other physiological pressures. The catheter is intended for short term peripheral access to the central venous system.

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Technological Characteristics:

The technological characteristics of the ReavillMED device are compatible to those of the following predicate devices.

Utah Medical Disposable Pressure Transducer (K841788):

- Intended use
- Sensor materials
- Wire connector material
- Housing assembly materials
- Operating pressure range
- Sensitivity
- Zero drift with time
- Unbalance
- Overpressure protection
- Operating temperature
- Excitation voltage & frequency
- Operating life
- Storage temperature
- Defibrillation withstand
- Phase shift
- Output impedance
- Input impedance
- Sterility
- Leakage current
- Natural frequency

Utah Medical Pressure Monitoring Line (K842352):

- Intended use
- Tubing connectors material
- Pressure tubing material
- Dimensions
- Hardness
- Sterility
- Performance

Poly RADPICC (K031129):

- Intended Use
- ISO 10553 Parts 1 and 3
- Sterility
- Dimensional diameter and length

UMBILI-CATH-P (K940871):

- Intended Use
- Material
- Sterility
- ISO 10553 Parts 1 and 3
- Contact duration

Non Clinical Data Summary:

The following testing was performed on the ReavillMED Blood Pressure Monitoring Device

Testing Performed	Standard	Acceptance Criteria	Results
Sensor Testing	ANSI/AAMI BP-22, 1994	• Operating Pressure Range: -50 mmHg to +300 mmHg • Sensitivity: 5μV/V/mmHg, +/- 2% (typically < +/- 1%) • Zero Drift with Time: +1.0 mmHg/8 hours after 10 minute warm up to operating temperature • Leakage Current: <2μA @ 115 VAC RMS and 60 Hz • Unbalance: +75 mmHg	Meets Requirements
Sensor Testing (continued)	ANSI/AAMI BP-22, 1994	• Overpressure Protection: -400 mmHg to +4000 mmHg • Operating Temperature: 15 C to 40 C • Excitation Voltage and Frequency: 2 to 10 VDC or VAC RMS to 50kHz • Operating Life: >500 hours • Storage Temperature: -25 C to +65 C • Defibrillation Withstand: 5 discharges/5 minutes of 360 joules @ 50 Ω load • Natural Frequency: > 20 Hz in saline • Phase Shift: < 5 degrees at 5 Hz • Output Impedance: 270 Ω to 400 Ω • Input Impedance: 270 Ω to 400 Ω	Meets Requirements

Attachment 1

Non Clinical Data Summary (continued):

Testing Performed	Standard	Acceptance Criteria	Results
Luer taper and lock fittings	ISO 594-1	• Concial fitting and 6% luer taper • Liquid leakage from fitting assembly under pressure • Air leakage into fitting assembly during aspiration • Separation force of fitting assembly • Unscrew torque of fitting assembly • Ease of assembly • Resistance to overriding	Meets Requirements
Tensile Testing	ISO 10555 Parts 1 and 3	• Minimum break force of 4N (or 0.89923 lbs of force)	Meets requirements
Biocompatibility testing (Monitoring Line)	ISO 10993-1	• Cytotoxicity • Sensitization • Irritation/Intracutanious Reactivity • Systematic Toxicity • Hemocompatibility	Meets requirements
Biocompatibility testing (Catheter)	ISO 10993-1	• Cytotoxicity • Sensitization • Irritation Reactivity • Systematic Toxicity • Hemolysis • Implantation • Genotoxicity	Meets requirements
Risk Analysis	ISO 14971	• No unacceptable risks	Acceptable
EtO sterilization validation	ANSI/AAMI/ISO 11135-1	• No growth of the test organism from any of the processed indicators for ethylene oxide sterilization • following incubation.	To be performed prior to product release
EtO residual testing	ISO 10993-7	• EO = 60mg/30days • ECH = 60mg/30days	To be performed prior to product release

Conclusions:

The indications for use are consistent with the previously indicated predicate devices and in the applicable FDA classification regulation. Differences in technological characteristics from those of the cited predicate devices do not raise new issues of safety or effectiveness and are addressed in the submission. The product meets the following standards:

- ANSI/AAMI BP-22, 1994
- ISO 594-1
- ISO 10555 Parts 1 and 3
- ISO 10993-1
- ISO 14971
- ANSI-AAMI/ISO 11135-1
- ISO 10993-7

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Michele Vovolka
Vice President, Quality Operations
ReavillMED
888 East Belvidere Road, Suite 212
Grayslake, Illinois 60030

DEC 2 2 2010

Re: K101189
Trade/Device Name: ReavillMED Blood Pressure Monitoring System
Regulation Number: 21 CFR 870.2850
Regulation Name: Extravascular Blood Pressure Transducer
Regulatory Class: II
Product Code: DRS, LJS
Dated: November 18, 2010
Received: November 19, 2010

Dear Ms. Vovolka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

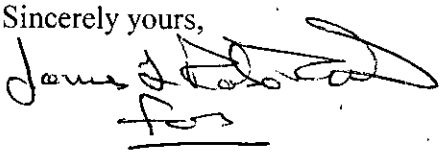
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

DEC 2 2 2010

510(k) Number (if known): K101189

Device Name: ReavillMED Blood Pressure Monitoring System

Indications for Use:

The ReavillMED product is combination product containing a pressure monitoring system and a peripherally inserted central catheter. The pressure monitoring system is intended for continuous measurement of blood pressures or other physiological pressures. The catheter is intended for short term peripheral access to the central venous system.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

12/22/10

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control and Dental Devices
510(k) Number
K101189